

THE WHITE HOUSE
WASHINGTON

January 20, 2001

MEMORANDUM FOR THE HEADS AND ACTING HEADS OF EXECUTIVE
DEPARTMENTS AND AGENCIES

FROM: ANDREW H. CARD, JR. *Andrew H. Card, Jr.*
Assistant to the President
and Chief of Staff

SUBJECT: Regulatory Review Plan

The President has asked me to communicate to each of you his plan for managing the Federal regulatory process at the outset of his Administration. In order to ensure that the President's appointees have the opportunity to review any new or pending regulations, I ask on behalf of the President that you immediately take the following steps:

1. Subject to any exceptions the Director or Acting Director of the Office of Management and Budget (the "OMB Director") allows for emergency or other urgent situations relating to health and safety, send no proposed or final regulation to the Office of the Federal Register (the "OFR") unless and until a department or agency head appointed by the President after noon on January 20, 2001, reviews and approves the regulatory action. The department or agency head may delegate this power of review and approval to any other person so appointed by the President, consistent with applicable law.
2. With respect to regulations that have been sent to the OFR but not published in the Federal Register, withdraw them from OFR for review and approval as described in paragraph 1, subject to exception as described in paragraph 1. This withdrawal must be conducted consistent with the OFR procedures.
3. With respect to regulations that have been published in the OFR but have not taken effect, temporarily postpone the effective date of the regulations for 60 days, subject to exception as described in paragraph 1.

ADM-024

4. Exclude from the requested actions in paragraphs 1-3 any regulations promulgated pursuant to statutory or judicial deadlines and identify such exclusions to the OMB Director as soon as possible.
5. Notify the OMB Director promptly of any regulations that, in your view, impact critical health and safety functions of the agency and therefore should be also excluded from the directives in paragraphs 1-3. The Director will review any such notifications and determine whether exception is appropriate under the circumstances.
6. Continue in all instances to comply with Executive Order 12866, pending our review of that order, as well as any other applicable Executive Orders concerning regulatory management.

As used in this memorandum, "regulation" has the meaning set out in section 3(e) of Executive Order 12866. That is, this plan covers "any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking."

This regulatory review will be implemented by the Director or Acting Director of the OMB. Communications regarding exceptions to the review, or questions regarding the review generally, should be addressed to that individual.

Finally, in the interest of sound regulatory practice and the avoidance of costly, burdensome, or unnecessary regulation, independent agencies are encouraged to participate voluntarily in this review.

This memorandum shall be published in the Federal Register.

U.S. NUCLEAR REGULATORY COMMISSION

DIRECTIVE TRANSMITTAL

TN: DT-00-12

To: NRC Management Directives Custodians

Subject: Transmittal of Directive 6.3, "The Rulemaking Process"

Purpose: Directive 6.3 is being revised in its entirety to reflect the change in the delegation of the rulemaking function from the Office of Nuclear Regulatory Research to the Offices of Nuclear Material Safety and Safeguards and Nuclear Reactor Regulation, to expand and clarify NRC organizational responsibilities during the rulemaking process, and to incorporate changes in the rulemaking process that have occurred since the last complete revision of this directive.

Office and Division of Origin: Office of Administration

Contact: Mike Lesar, 415-7163

Date Approved: January 26, 1995 (Revised: June 2, 2000)

Volume: 6 Internal Management

Directive: 6.3 The Rulemaking Process

Availability: Rules and Directives Branch
Office of Administration
David L. Meyer (301)415-7162 or
Doris Mendiola (301)415-6297

The Rulemaking Process

Directive 6.3

Contents

Policy	1
Objectives	1
Organizational Responsibilities and Delegations of Authority	1
Commission	1
Executive Director for Operations (EDO)	2
Chief Financial Officer (CFO)	2
Chief Information Officer (CIO)	3
Inspector General (IG)	3
General Counsel (GC)	4
Director, Office of Congressional Affairs (OCA)	4
Director, Office of Public Affairs (OPA)	5
Director, Office of Enforcement (OE)	5
Director, Office of Administration (ADM)	5
Director, Lead Office	6
Director, Office of State and Tribal Programs (STP)	7
Chairs, Advisory Committees	8
Directors, Concurring Offices	8
Office Representative (or Alternate)	9
Rulemaking Plan	9
Working Group	11
Concurrences	12
Office Concurrence	12
OGC Concurrence	13
OGC No Legal Objection	13

Contents (continued)

Coordination With Agreement States	14
Reports	15
Rulemaking Identification Number (RIN)	16
Applicability	16
Handbook	16
Definitions	16
References	17



U. S. Nuclear Regulatory Commission

Volume: 6 Internal Management

ADM

The Rulemaking Process Directive 6.3

Policy (6.3-01)

It is the policy of the U.S. Nuclear Regulatory Commission to develop quality rules that are consistent with the requirements of all applicable laws and regulations and to ensure increased efficiencies in its rulemaking process.

Objectives (6.3-02)

- To ensure that schedules for rulemaking actions are established and met. (021)
- To ensure coordination among offices and the efficient use of staff resources during the development of rulemaking actions. (022)
- To ensure that Agreement States are provided an opportunity to comment on draft rulemaking plans and rulemaking actions. (023)
- To provide maximum opportunity for the full and robust participation by the public and stakeholders in rulemaking proceedings. (024)

Organizational Responsibilities and Delegations of Authority (6.3-03)

Commission (031)

- Directs the initiation of rulemaking activities. (a)
- Approves or denies each rulemaking plan, or major modification to a plan, not under the authority delegated to the Executive Director

Volume 6, Internal Management
The Rulemaking Process
Directive 6.3

Commission
(031) (continued)

for Operations (EDO), the Chief Financial Officer (CFO), or the Chief Information Officer (CIO). (b)

- Approves or denies each proposed and final rule not under the authority delegated to the EDO, CFO, or CIO. (c)

Executive Director for Operations (EDO)
(032)

- Approves the rulemaking plan, or any modifications to the plan, for each rulemaking that will be issued under the authority delegated to the EDO. (a)
- Directs the initiation of rulemakings within the scope of the authority delegated to the EDO, as appropriate. (b)
- If necessary, resolves issues preventing office concurrence on a rulemaking. (c)
- Within 20 calendar days of receipt of a proposed rule or a final rule—(d)
 - Transmits the rule for Commission action. (i)
 - If necessary, returns the rule to staff for modification or resolution of questions within a specified schedule. (ii)
 - If appropriate, notifies the Commission of the intent to issue the rule under the authority of the EDO. (iii)

Chief Financial Officer (CFO)
(033)

- Reviews rulemaking plans and all proposed and final rule documents to ensure that—(a)
 - Resources required to complete and implement the rulemaking have been fully and properly addressed. (i)
 - Rulemakings that have a potential to affect the agency's license fee and annual fee schedules have been coordinated. (ii)

Chief Financial Officer (CFO)

(033) (continued)

- Forwards comments on rulemaking plans and proposed and final rules to the lead office. (b)
- Approves the rulemaking plan, or any modifications to the plan, for each rulemaking that will be issued under the authority delegated to the CFO. (c)
- If a rulemaking will be issued under the authority delegated to the CFO, directs the preparation of the rulemaking plan, the *Federal Register* notices, and all required supporting documents. (d)

Chief Information Officer (CIO)

(034)

- Reviews rulemaking plans and all proposed and final rule documents to ensure that information technology effects of the rulemaking have been adequately evaluated and addressed and to ensure compliance with the information collection requirements of the Paperwork Reduction Act and the agency's policies and procedures governing information management. (a)
- Forwards comments on rulemaking plans and proposed and final rules to the lead office. (b)
- Approves the rulemaking plan, or any modifications to the plan, for each rulemaking that will be issued under the authority delegated to the CIO. (c)
- If a rulemaking will be issued under the authority delegated to the CIO, directs the preparation of the rulemaking plan, the *Federal Register* notices, and all required supporting documents. (d)

Inspector General (IG)

(035)

- Reviews rulemaking actions and makes recommendations concerning the effect of rulemaking actions on the economy and the efficiency of programs and operations administered or financed by the NRC or the prevention of fraud and abuse in these programs. (a)

Volume 6, Internal Management
The Rulemaking Process
Directive 6.3

Inspector General (IG)
(035) (continued)

- Forwards comments to the lead office or Commission, as appropriate. (b)

General Counsel (GC)
(036)

- Analyzes each request for a rulemaking action for legal sufficiency. (a)
- Reviews rulemaking actions in accordance with Office of the General Counsel (OGC) Policy and Procedure Directive Number 14 governing review and approval of papers. (b)
- Reviews rulemaking actions to ensure that they are consistent with current rules and other authoritative statements of NRC policy, including, for example, consistency in the use of wording, terminology, definitions, and risk standards. (c)
- Forwards comments on rulemaking plans, including OGC's analysis of legal sufficiency, demonstrating that no known basis exists for a legal objection to the lead office. (d)
- Forwards comments on rulemaking documents to the lead office or Commission, as appropriate. (e)
- Designates a staff attorney to be available to provide legal advice and support. (f)

Director, Office of Congressional Affairs (OCA)
(037)

- Keeps Congress fully and currently informed of all NRC activities, including rulemaking actions. (a)
- Signs and transmits the letters and forms to Congress concerning NRC rulemaking actions. (b)

Director, Office of Public Affairs (OPA)
(038)

- Determines whether a press release is needed for a rulemaking action. (a)
- If a press release is needed, designates an OPA representative to prepare a draft press release for comment and review by the lead office. (b)

Director, Office of Enforcement (OE)
(039)

- Determines whether changes to the NRC Enforcement Policy are needed because of the rulemaking action. (a)
- Determines whether the criminal penalties section for each part affected by the rulemaking action must be amended to reflect the action. (b)
- Ensures that *Federal Register* notices include an appropriate criminal penalty statement. (c)

Director, Office of Administration (ADM)
(0310)

- Informs the EDO of a rulemaking initiated by offices not reporting to the EDO if the rulemaking will require resource planning by the EDO. (a)
- Provides central coordination and oversight for the NRC rulemaking program, including chairing meetings of the Rulemaking Coordinating Committee. (b)
- Assigns the rulemaking identification number (RIN) (see paragraph 6.3-09) of this directive). (c)
- Maintains the NRC Rulemaking Website. (d)
- Reviews rulemaking actions to ensure compliance with the Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act of 1996, Federal Register Act, 1 CFR Chapters I and II, and the President's memorandum of June 1, 1998, on plain language

Volume 6, Internal Management
The Rulemaking Process
Directive 6.3

Director, Office of Administration (ADM)
(0310) (continued)

and to ensure that the rulemaking actions are consistent with current regulations and other authorization statements of agency policy including, for example, consistency in the use of wording, terminology, and definitions. (e)

- Forwards comments on rulemaking plans and rulemaking actions to the lead office. (f)
- Receives and processes petitions for rulemaking, including determining whether the petition includes the information required in 10 CFR 2.802(c); docketing; and preparing a notice of receipt to be published in the *Federal Register*. (g)

Director, Lead Office
(0311)

- Initiates and develops each element of a rulemaking action in subject areas for which the office is responsible. (a)
- Designates an office representative for each rulemaking action that coordinates the rulemaking action; leads a working group, as appropriate; leads the preparation of the rulemaking plan, the *Federal Register* notices, and the required supporting documents; and obtains necessary concurrences. (b)
- Establishes a working group, as appropriate, to assist in the preparation of the rulemaking plan and the proposed and final rule packages and in obtaining necessary concurrences. (c)
- In consultation with OGC and other offices that will participate in the rulemaking, prepares a rulemaking plan for each contemplated rulemaking (see paragraph (042) of this directive for circumstances where a rulemaking plan is not needed). The rulemaking plan must include a basis for and an indication of whether the rulemaking action will be a "major rule" as defined in the Small Business Regulatory Enforcement Fairness Act, or other law (see the NRC Regulations Handbook, NUREG/BR-0053, Appendix F, for a definition of the term major rule and an explanation of the requirements of this act). (d)
- Determines the offices from which office concurrence will be requested on the rulemaking plan and the *Federal Register* notices. (e)

Director, Lead Office
(0311) (continued)

- Ensures that draft rulemaking plans and *Federal Register* notices that have a significant impact on NRC policy or program structure are submitted to the Office of the Inspector General at the interoffice coordination stage. (f)
- Coordinates rulemaking actions with other Government agencies (e.g., Environmental Protection Agency, Department of Energy) when such action is required by statute or regulation. (g)
- Recommends to the EDO whether or not to initiate the proposed rulemaking. (h)
- Informs the Commission via an information paper submitted by the EDO, CFO, or CIO of the draft rulemaking plan and makes the rulemaking plan available to the advisory committees, NRC staff, and to Agreement States (see paragraphs (071) and (072) of this directive for a discussion of when the NRC will issue a draft rulemaking plan). (i)
- For assigned rulemakings, prepares the *Federal Register* notices and the required supporting documents. (j)
- Solicits early Agreement State participation from a technical standpoint in the office's area of responsibility in applicable rulemakings through the Office of State and Tribal Programs. (k)
- Coordinates with OPA to determine whether a press release is appropriate and, if so, provides OPA with information sufficient to develop the press release and includes the draft OPA press release in the rulemaking package. (l)

Director, Office of State and Tribal Programs (STP)
(0312)

- Designates an office representative to participate in a working group, as appropriate, and to coordinate Agreement State participation. (a)
- Coordinates interaction with Agreement States for applicable rulemakings. (b)

Volume 6, Internal Management
The Rulemaking Process
Directive 6.3

Director, Office of State and Tribal Programs (STP)

(0312) (continued)

- Designates an office representative to participate in an NRC-Agreement State working group, as appropriate, and coordinates Agreement State participation in such a working group in accordance with MD 5.3, "NRC and Agreement State Working Groups." (c)
- Forwards responses received from the Agreement States to the lead office. (d)

Chairs, Advisory Committees

(0313)

As appropriate, review and provide comment to the lead office or Commission on the rulemaking plan and the proposed and final rule packages.

Directors, Concurring Offices

(0314)

- Designate an office representative and an alternate to coordinate each rulemaking action, including development of the rulemaking plan, and indicate whether the representative is authorized to provide office concurrence while participating as a member of the working group, and also designate other key staff, as necessary, to assist in developing documents necessary for the rulemaking. (a)
- Respond to lead office within 20 calendar days of the date of the transmittal memorandum with any questions or concerns regarding any technical analysis of information or data that may invalidate or raise doubts about the proposal. (b)
- Review rulemaking actions to ensure that they are consistent with current rules and other authoritative statements of agency policy including, for example, consistency in the use of wording, terminology, definitions, and risk standards. (c)
- Forward comments on rulemaking plans and rulemaking documents to the lead office. (d)
- Sign for his or her office regarding concurrence on the rulemaking action or delegate concurring authority to the designated working group member or other appropriate official. (e)

Office Representative (or Alternate)
(0315)

- The office representative for the lead office has the following responsibilities: (a)
 - Leads the activities of the working group. (i)
 - Prepares or coordinates the preparation of the rulemaking plan, the *Federal Register* notices, and required supporting documents. (ii)
 - Keeps office management informed of the status of the rulemaking or any policy issues that may arise. (iii)
 - Obtains necessary concurrences or coordinates the concurrence process. (iv)
- The office representative for concurring offices and OGC has the following responsibilities: (b)
 - Keeps office management informed of any policy issues that could affect office interests or that constitute a basis for legal objection. (i)
 - Oversees office reviews regarding factual matters in the concurrence document. (ii)
 - Interacts in the concurrence process either in the traditional role or as a member of a working group. (iii)
 - Oversees office development of rulemaking documents as assigned. (iv)

Rulemaking Plan
(6.3–04)

The rulemaking plan encompasses the following activities: (041)

- Defining the regulatory problem or issue to be resolved, and describing preliminary concepts of actions needed to resolve the problem (a)
- Providing OGC's analysis of legal sufficiency, demonstrating that no known bases exist for a legal objection (b)

Rulemaking Plan

(6.3-04) (continued)

- Providing the rationale that the rulemaking will be cost-effective and will meet backfit rule criteria, where appropriate, and indicating whether the rulemaking will be a major rule (c)
- Indicating whether any known Agreement State issues exist (d)
- Discussing the basis for and the proposed Agreement State compatibility classifications for the rulemaking action, if appropriate (e)
- Identifying supporting documents (f)
- Identifying resources required to complete and implement the rulemaking (g)
- Indicating whether the lead office recommends that the EDO issue the rulemaking (h)
- Identifying the lead office staff and staff of participating offices, including the office representative and an alternate, who will be involved in the rulemaking process (i)
- Identifying, if appropriate, members of a working group (j)
- Specifically addressing whether enhanced public participation should be employed in the rulemaking process and when an enhanced effort is to be used (If enhanced public participation is contemplated, the plan must provide more detail on planning time and resources necessary to conduct the rulemaking effectively. The plan also must describe special measures or procedures to be employed [e.g., whether the rulemaking is a negotiated rulemaking].) (k)
- Providing schedules for preparing supporting documents and completing the proposed rule and comment evaluation process (l)

A rulemaking plan is not needed if: (042)

- The Commission specifically directs the initiation of a rulemaking action. The lead office is responsible for notifying STP who in turn informs the Agreement States, when applicable. (a)

Rulemaking Plan

(6.3-04) (continued)

- The issue to be resolved is of sufficient urgency that the lead office director, OGC, and the EDO will exercise direct oversight of the writing of the rule. The EDO formally notifies the Commission of this activity usually via an information paper, provides a rationale for proceeding without a rulemaking plan, and obtains approval from the Commission. The lead office is responsible for notifying STP who in turn informs the Agreement States, when applicable. The proposed rule is submitted to the Commission for approval. This need to obtain Commission approval for not preparing a rulemaking plan does not diminish the authorities specifically delegated to the office directors, OGC, and the EDO regarding matters that are a significant threat to public health and safety. (b)
- The issue is addressed through the issuance of a direct final rule. (c)
- The rulemaking action is purely administrative or corrective in nature. (d)

Working Group

(6.3-05)

If a working group is appropriate for a specific rulemaking action, staff from the lead office, concurring offices, and OGC comprise the working group.

- A working group should have—(051)
 - A task leader from the lead office (a)
 - A member from other branches within the lead office that have program responsibilities related to the rulemaking (b)
 - A member from OGC to be available to provide legal advice and support (c)
 - Staff from other offices, as appropriate (If the involvement of another office in a rulemaking is limited to a specific area, such as matters related to regulatory flexibility, information collection, Agreement State compatibility, or enforcement, the involvement of the working group member from that office may be limited to that specific area.) (d)

Working Group

(6.3-05) (continued)

- The working group is responsible for—(052)
 - Assessing the scope of the rulemaking action, identifying the tasks necessary to complete the rulemaking action, identifying members responsible for completing these tasks, and developing schedules and resource estimates for completing each stage of the action (a)
 - Assisting the lead office in the preparation of the rulemaking plan, the proposed and final rule packages, and all necessary supporting documents (b)
 - Addressing comments, estimating the information collection burden, and preparing briefing materials (c)
 - Reviewing contractor reports or monitoring contractor effort if contract support is necessary (d)
 - Preparing associated guidance, including licensing, inspection, and enforcement guidance, as appropriate, and coordinating the completion of the guidance documents so that the final guidance is available when the final rule becomes effective (e)
 - Facilitating the concurrence process (f)

Concurrences

(6.3-06)

Office Concurrence

(061)

- Office concurrence means that the concurring office—(a)
 - Agrees with the overall approach, objective, and technical content, and resource impacts of the rulemaking action (i)
 - Believes that the rulemaking action will not adversely affect or conflict with other NRC programs and policies in their area of responsibility (ii)
 - Agrees that the material for which the office has a programmatic basis for judgment is factual and accurate (iii)

Office Concurrence
(061) (continued)

- Office concurrence on rulemaking plans and *Federal Register* notices is requested from—(b)
 - All other NRC offices that are affected by or interested in the rulemaking action from a technical standpoint in their area of responsibility (i)
 - OGC (ii)
 - Rules and Directives Branch, ADM (iii)
 - Information Management Branch, OCIO (iv)
 - OE (v)
 - OCFO (vi)

OGC Concurrence
(062)

OGC concurrence means that from OGC's standpoint, the recommended action is—

- Legally sufficient (a)
- Consistent with existing Commission policy (b)
- Supported by OGC (c)

OGC No Legal Objection
(063)

No legal objection means that—

- The recommended action is legally sufficient (a)
- OGC is not taking a position with respect to the policy aspects of the recommendation (b)

Coordination With Agreement States

(6.3-07)

- For rulemakings that may affect Agreement States, the director of the lead office—(071)
 - In consultation with the appropriate NRC offices and OGC, develops a draft rulemaking plan that includes suggested Agreement State compatibility classifications for the proposed rule (If the compatibility classification for Agreement State regulations is “C” or “H and S,” which is explained in Management Directive 5.9, “Adequacy and Compatibility of Agreement State Programs,” the essential objectives of each section of the proposed rule need to be identified. [Also see STP Procedure SA-200, “Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements.”]) (a)
 - After office concurrence on the draft rulemaking plan, submits the rulemaking plan to the EDO, CFO, or CIO, as appropriate (The EDO, CFO, or CIO provides a copy of the draft rulemaking plan to the Commission via an information paper.) (b)
 - When the information paper is submitted to the Commission, provides the draft rulemaking plan, marked in block form **PREDECISIONAL DRAFT INFORMATION, FEDERALLY PROTECTED, NOT FOR PUBLIC DISCLOSURE**, to STP (STP will provide the Agreement States 45 days to comment, following STP Procedure SA-800, “Providing NRC Predecisional Documents to Agreement States.”) (c)
 - Notifies the Council Chair of the Conference of Radiation Control Program Directors (CRCPD), who has responsibility for the Suggested State Regulations (SSRs), through the Technical Conference Forum (<http://techconf.llnl.gov>) via the NRC Home Page (<http://www.nrc.gov>) (d)
 - In concert with the appropriate NRC offices and OGC, revises the draft rulemaking plan in response to comments received from the Agreement States and CRCPD (e)
 - Provides the revised plan to the Commission for approval, including staff’s disposition of the Agreement State and CRCPD comments (f)

Coordination With Agreement States

(6.3-07) (continued)

- If the Commission approves the rulemaking plan, notifies the CRCPD Council Chair, who has responsibility for SSRs, so that development of an SSR, if desired, may parallel the rulemaking through the Technical Conference Forum (<http://techconf.llnl.gov>) via the NRC Home Page (<http://www.nrc.gov>) (g)
- If the Commission does not approve the rulemaking plan, notifies STP and the CRCPD Council Chair of the plan's disapproval through the Technical Conference Forum (<http://techconf.llnl.gov>) via the NRC Home Page (<http://www.nrc.gov>) (h)
- For rulemakings that may affect Agreement States, the Director, STP—(072)
 - Makes available the predecisional draft rulemaking plan to the Agreement States and allows 45 days for their comments, according to STP Procedure SA-800, through the Technical Conference Forum (<http://techconf.llnl.gov>) via the NRC Home Page (<http://www.nrc.gov>). The lead office project manager also has access to this separate area of the Technical Conference Forum. If a rulemaking plan is not needed, notifies Agreement States of the rulemaking action (a)
 - After the expiration of 45 days, provides to the lead office any comments received directly by STP from Agreement States (b)
 - Notifies the Agreement States of the Commission's approval or disapproval of the rulemaking plan (c)

Reports

(6.3-08)

The Rules and Directives Branch (RDB), ADM, is responsible for preparing—

- The NRC Regulatory Agenda and the Unified Agenda of Regulatory and Deregulatory Actions (a)
- The annual Regulatory Plan submitted to the Office of Management and Budget required by Executive Order 12866 (b)

Reports

(6.3-08) (continued)

- The semiannual report to the EDO on the status of all petitions for rulemaking (c)
- The Rulemaking Activity Plan that is submitted to the Commission for approval that contains the priorities, schedules, and resources for all approved rulemakings (d)
- The monthly supplements to the NRC Rules and Regulations and reviews the Office of the Federal Register's annual compilation of 10 CFR, Chapter 1 (e)

Rulemaking Identification Number (RIN)

(6.3-09)

The RIN is assigned after a rulemaking plan is approved by the Commission or when a draft of the rulemaking action is submitted to the Rules and Directives Branch for review.

Applicability

(6.3-10)

The policy and guidance in this directive and handbook apply to all NRC headquarters and regional employees who are involved in the rulemaking process.

Handbook

(6.3-11)

NUREG/BR-0053, "NRC Regulations Handbook," is the handbook for this directive. It contains a description of the legal requirements for rulemaking and NRC's basic internal procedures.

Definitions

(6.3-12)

Advisory Committees. Advisory committees include the Advisory Committee on Reactor Safeguards, the Advisory Committee on the Medical Uses of Isotopes, and the Advisory Committee on Nuclear Waste.

Lead Office. The lead office for a rulemaking action is the office assigned the responsibility for a rulemaking action, including preparation of the rulemaking plan, the proposed and final rule packages, and any required supporting documents.

References

(6.3-13)

Administrative Procedure Act (5 U.S.C. 551 et seq.).

Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 et seq.).

Code of Federal Regulations

Title 1, "General Provisions."

Title 10, "Energy."

Energy Reorganization Act of 1974, as amended (42 U.S.C. 5801 et seq.).

Executive Order 12866, "Regulatory Planning and Review," September 30, 1993.

Federal Register Act (5 U.S.C. Chapter 15).

National Environmental Policy Act (42 U.S.C. 4321 et seq.).

NRC Management Directive (MD) 5.3, "NRC and Agreement States Working Groups."

— 5.9, "Adequacy and Compatibility of Agreement State Programs."

— 9.17, "Organization and Functions, Office of the Executive Director for Operations."

NRC Policy Statement on Adequacy and Compatibility of Agreement State Programs, approved by the Commission, June 30, 1997 (62 FR 46517; September 3, 1997).

—, SECY-94-141, "Improvement of the Rulemaking Process," May 23, 1994.

—, Staff Requirements Memorandum, from John C. Hoyle to James M. Taylor, COMSECY-96-0357 – SECY-96-034, "Interactions With the Agreement States in Rulemaking Planning," June 11, 1996.

—, Staff Requirements Memorandum, from John C. Hoyle to William C. Parler and James M. Taylor, SECY-94-141, "Improvement of the Rulemaking Process," June 28, 1994.

NUREG/BR-0053, "NRC Regulations Handbook," Rev. 4, September 1997. (Note: Revision 5 will reflect revised MD 6.3.)

NUREG/BR-0058, "Regulatory Analysis Guidelines of the USNRC," Rev. 2, November 1995.

Volume 6, Internal Management
The Rulemaking Process
Directive 6.3

References

(6.3-13) (continued)

NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," January 1997.

Office of the General Counsel Policy and Procedure Directive Number 14, "OGC Review and Signoff of Papers."

STP Internal Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

— SA-800, "Providing NRC Predecisional Documents to Agreement States."

Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

Presidential Memorandum for the Heads of Executive Departments and Agencies, "Plain Language in Government Writing," June 1, 1998.

Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121).

NUREG/BR-0053, Revision 4

**United States
Nuclear Regulatory Commission**

Regulations Handbook

Edited by: M. T. Lesar

September 1997

**Division of Administrative Services
Office of Administration**



PART 1 - THE NRC RULEMAKING PROCESS

	<u>Page</u>
1.1 Administrative rulemaking.....	2
1.3 NRC rulemaking.....	5
1.5 Rulemaking initiation.....	6
1.7 The rulemaking plan.....	9
1.9 Agreement State review.....	13
1.11 Advisory committee review.....	15
1.13 Concurrence on a rulemaking action.....	16
1.15 Scheduling concurrences.....	19
1.17 Commission consideration.....	22
1.19 Processing for publication.....	23
1.21 Timely resolution of petitions for rulemaking.....	25

1.1 Administrative rulemaking.

(a) The Administrative Procedure Act.

(1) The Administrative Procedure Act of 1946 (APA), as amended, presents the minimum procedural requirements that Federal agencies are required to follow when they promulgate rules and conduct adjudicatory proceedings. The APA --

(i) Provides the public, with stated exceptions, the right to participate in the rulemaking process by commenting on proposed rules;

(ii) Requires that the effective date of a regulation be not less than 30 days from the date of publication unless there is good cause for an earlier date;

(iii) Provides for the publication of agency statements of organization and procedural rules; and

(iv) Establishes the standard of judicial review of administrative actions.

(2) The primary goal of the APA is to ensure that agencies observe procedural due process (i.e., fairness) in conducting their regulatory and administrative affairs. Appendix B to this handbook sets out the provisions of the APA that govern notice and comment rulemaking (5 U.S.C. 553).

(3) In establishing minimum procedural requirements, the APA permits agency flexibility in developing additional procedural requirements. These requirements can be found for each agency in the Code of Federal Regulations (CFR). The additional rulemaking policies for the Nuclear Regulatory Commission (NRC) appear in Management Directive (MD) 6.3, "The Rulemaking Process." A description of the legal requirements for rulemaking and NRC's basic internal procedures are discussed in more detail in this part of this handbook.

(4) Enabling legislation for an agency, specific acts that an agency administers, or judicial decisions resulting from legal challenges to agency actions may require the agency to follow additional procedural requirements in developing its regulations.

(b) The Code of Federal Regulations.

(1) The CFR is a codification of the regulations promulgated by Federal agencies. The CFR is edited annually to present the regulations effective as of the revision date of the volume. The CFR, used in conjunction with the daily Federal Register, provides a current version of an agency's regulations.

(2) The CFR is divided into 50 titles according to subject matter. These titles are divided into chapters, chapters are divided into parts, and parts are divided into sections. NRC regulations are contained in Title 10, "Energy," Chapter I, "Nuclear Regulatory Commission," Parts 0-199. Each part has a heading that reflects its content. Each part sets out the regulations that pertain to a regulatory activity or program of the NRC. Some parts set out procedural requirements and information pertaining to internal agency organization and procedures that describe how the agency conducts its activities. The NRC has not used all of the parts between 0 and 199. The unused parts are reserved for future NRC use.

(c) The Federal Register.

(1) The Federal Register is published each Federal workday by the Office of the Federal Register (OFR), National Archives and Records Administration. The Federal Register provides a uniform system for publishing Presidential documents, final rules, proposed rules, advance notices of proposed rulemaking, petitions for rulemaking, general notices, policy statements, semiannual agendas of regulations, meeting announcements, and other agency documents

concerning the conduct of public business. These documents are discussed in subsequent sections of this handbook.

(2) The publication of a document in the Federal Register has certain legal effects.

(i) Publication provides official notice of a document's existence and content.

(ii) Publication creates a rebuttable presumption that the text is a true copy of the original document and that the document was duly issued, prescribed, and promulgated.

(iii) The contents of the Federal Register are judicially noticed by a court of law.

(3) The OFR's publication requirements for the different types of documents published in the Federal Register are covered in this handbook. However, the OFR may occasionally modify these requirements. Questions regarding the most current OFR requirements for publication or special publication requests should be directed to the Rules and Directives Branch (RDB), Office of Administration (ADM) (415-7163).

1.3 NRC rulemaking.

(a) The NRC may develop a regulation in response to --

(1) Congressional promulgation of a new statute requiring new regulatory requirements;

(2) Commission or NRC staff initiatives indicating a need for further regulation to resolve a safety, safeguards, or environmental problem; or

(3) The receipt of a petition for rulemaking.

(b) The NRC complies with the laws and regulations applicable to the rulemaking process as it develops a regulation.

(c) The NRC has established policy governing the rulemaking process in MD 6.3. The policies established in the directive and the procedures of this handbook are intended to ensure that --

(1) Responsibilities are established for all NRC offices and employees who are involved in the rulemaking process;

(2) Schedules for rulemaking actions are established and met;

(3) Coordination occurs among NRC offices during the development of a rulemaking action;

(4) NRC staff resources are used efficiently in developing rules; and

(5) Agreement States are provided an early opportunity to comment on draft rulemaking plans and rulemaking actions.

1.5 Rulemaking initiation.

(a) Applicability. The procedures in this section apply to all NRC headquarters and regional employees who are involved in the rulemaking process.

(b) Rulemaking plan. If an office that is subject to the procedures described in this section desires to recommend the initiation of a rulemaking action, the office shall submit a memorandum to the Office of Nuclear Regulatory Research (RES) that presents the request.

(1) RES shall prepare a rulemaking plan as described in Section 1.7 of this handbook.

(2) RES shall prepare a memorandum to the Executive Director for Operations (EDO) that transmits the rulemaking plan and recommends whether the rulemaking action is justified or not on the basis of information contained in the rulemaking plan.

(c) Commission action. If the Commission directs the staff to undertake a rulemaking action, the staff shall request that RES develop a rulemaking plan for the action to the extent practicable. A Commission paper that recommends rulemaking should not be prepared before following the procedures in this section and before considering the need for public participation.

(d) Rulemaking plan approval.

(1) The EDO approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that would be issued under the rulemaking authority delegated to the EDO by the Commission. (See MD 9.17, "Organization and Functions, Office of the Executive Director for Operations.")

(2) The Chief Financial Officer (CFO) approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that would be issued under the rulemaking authority delegated to the CFO by the Chairman

(see the memorandum from the Chairman to the Acting Chief Financial Officer dated February 18, 1997).

(3) The Chief Information Officer (CIO) approves or denies the rulemaking plan, or any modifications to the plan, for each rulemaking that would be issued under the rulemaking authority delegated to the CIO by the Chairman (see the memorandum from the Chairman to the Chief Information Officer dated June 13, 1997).

(4) The Commission approves or denies the rulemaking plan, or major modifications to a plan, for any rulemaking that is not within the authority delegated to the EDO, the CFO, or the CIO.

(e) Rulemaking plan unnecessary. A rulemaking plan is not required for rulemaking actions in certain situations.

(1) A rulemaking plan is not required if the rulemaking action is purely administrative in nature.

(2) A rulemaking plan is not required if the issue to be resolved is of sufficient urgency that the office directors, the Office of the General Counsel (OGC), and the EDO, the CFO, or the CIO will exercise direct oversight in the development of the rule. In this type of situation, the EDO, CFO, or CIO formally notifies the Commission of the rulemaking activity, provides a rationale for proceeding without a rulemaking plan, obtains Commission approval for the action, and provides the plans for notifying Agreement States, when applicable.

(i) Each proposed rule developed under these conditions must be submitted to the Commission for approval.

(ii) The need to obtain Commission approval for proceeding without preparing a rulemaking plan does not diminish the authorities specifically

delegated to the EDO, OGC, and office directors regarding matters that are a significant threat to public health and safety.

1.7 The rulemaking plan.

(a) RES, with the assistance of OGC, the office requesting the rulemaking, and the offices participating in the rulemaking, shall develop a proposed rulemaking plan for each contemplated rulemaking. RES is responsible for developing the rulemaking plan even if another office has lead responsibility for the rulemaking.

(b) The proposed rulemaking plan must contain the following types of information:

(1) The plan must define the regulatory problem or issue that is to be resolved through the rulemaking action. This definition may identify a safety concern, the need to facilitate the licensing process, or the need to provide relief of an unnecessary regulatory burden. The definition must include --

(i) A description of the existing regulatory framework; and

(ii) An explanation of why the NRC or the licensees cannot take actions to resolve the problem effectively within the existing regulatory framework.

(2) The plan must include an OGC analysis of legal sufficiency. The OGC analysis must demonstrate that there are no known bases for legal objection to the contemplated rulemaking. The analysis also must describe any potential legal complications identified by OGC that should be anticipated.

(3) The plan must provide the basis for believing that the contemplated rulemaking is likely to be cost-effective and will meet backfit criteria, if appropriate. This conclusion should be reached by considering the preliminary regulatory analysis of available information.

(4) The plan must indicate whether there are any known problems that could affect Agreement State implementation of the contemplated rulemaking action. If the rulemaking may affect Agreement States, the plan must include a suggested Agreement State compatibility classification for the proposed rule.

If the compatibility classification for Agreement State regulations is "C" or "H&S," the plan must identify the essential objectives of each section of the proposed rule. Agreement States will be provided an opportunity to comment on the draft rulemaking plan through the procedures presented in Section 1.9 of this handbook.

(5) The plan must identify the supporting documents that must be developed to complete and to implement the contemplated rulemaking action. Supporting documents could include a generic environmental impact statement (GEIS); the clearance package necessary to obtain Office of Management and Budget (OMB) approval of new or amended information collection requirements; regulatory impact analyses, including information sufficient either to constitute a regulatory flexibility analysis or to support a certification that the proposed regulation will not have a significant economic impact on a substantial number of small entities as required by the Regulatory Flexibility Act; and other related documents such as regulatory guides, NUREGs, or inspection plans.

(6) The plan must indicate whether the contemplated rulemaking will be a major rule, as defined by the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121) and provide a basis for the determination. (See Appendix F of this handbook for a definition of "major rule" and an explanation of the Act's requirements.)

(7) The plan must identify the resources that will be required to complete and to implement the contemplated rulemaking action, including the resources needed to develop all the supporting documents identified in paragraph (b)(5) of this section. The discussion must indicate whether these resources are included in the current five-year plan. This discussion must also identify the office that will be responsible for each activity.

(8) The plan must indicate whether the EDO, CFO, or CIO may issue the rule under the rulemaking authority delegated to the EDO, CFO, or CIO by the Commission.

(9) The plan must identify the lead office and name the key staff within each office who will be involved in the contemplated rulemaking action.

(i) The plan must identify the senior manager designated by each office director to concur for that office. Each designee is responsible for keeping the office director informed of key policy issues related to the rulemaking action.

(ii) The plan must indicate whether a steering group or working group format will be used to develop the contemplated rulemaking action.

(10) The plan must discuss whether enhanced public participation should be employed in the rulemaking process. The plan also must describe any special measures or procedures to be employed in the rulemaking process such as the issuance of a direct final rule or the use of negotiated rulemaking.

(11)(i) The plan must include a schedule for preparing the necessary supporting information, completing the proposed rule, analyzing public comment, and completing the final rule. The schedule must be established on the basis of --

(A) The priority or importance given to the action;

(B) The complexity of the issues to be resolved;

(C) The number and complexity of supporting documents, such as regulatory guides or the GEIS, or technical tools, such as computer codes needed for implementation; and

(D) The degree of interaction or negotiation with interested parties needed to complete the rulemaking.

(ii) Unless the contemplated rulemaking action would require the development of a GEIS or a regulatory guide, every effort should be made to

complete the rulemaking action within 18 months from the date the EDO approves initiation of the rulemaking.

(iii) A rulemaking plan should not be submitted when there are significant gaps in the technical basis for formulating or implementing the rule.

(c) RES shall make the rulemaking plan available to the appropriate advisory committee.

(d) The following actions are taken after the Commission or the EDO has approved a rulemaking plan.

(1) RES shall make the approved rulemaking plan available to the NRC staff through the NRC electronic rulemaking bulletin board system.

(2) ADM shall include a new regulatory agenda entry on the next version of the NRC Regulatory Agenda that is forwarded for inclusion in internal NRC electronic rulemaking bulletin board system. If the intended action will be a major rule, ADM shall include an entry for it in the NRC Regulatory Plan that is submitted to the OMB as required by Executive Order 12866.

(4) Each participating office will implement the plan as approved by the EDO. The office representative for each office will oversee the activities of his or her office so that the schedule is maintained.

1.9 Agreement State review.

(a)(1) After offices have concurred in the rulemaking plan, the Office of State Programs (OSP) provides the Agreement States with a copy of the plan, marked "pre-decisional." Agreement States have a 45-day comment period. If a rulemaking plan is not required, OSP notifies Agreement States of the rulemaking action.

(2) At the same time, the Conference of Radiation Control Program Directors (CRCPD) Council Chair that is responsible for suggested State regulations will be notified by the RES CRCPD point of contact.

(3) The Commission is provided with an information copy of the draft rulemaking plan.

(b) After consulting with the appropriate NRC offices and OGC, RES revises the draft rulemaking plan in response to comments submitted by Agreement States and the CRCPD. The revised plan is submitted to the Commission for approval. The submittal package contains an attachment that indicates the staff's disposition of Agreement State and CRCPD comments.

(c)(1) If the Commission approves the rulemaking plan the following actions are taken to inform Agreement States and the public of the staff's intention to proceed with the development of a proposed rule.

(i) RES places the approved plan on the electronic rulemaking bulletin board system.

(ii) RES creates an entry for the Regulatory Agenda and forwards the entry to the Office of Administration for inclusion in the next NRC Regulatory Agenda and the Unified Agenda of Regulatory and Deregulatory Actions.

(iii) The RES CRCPD point of contact notifies the CRCPD Council Chair responsible for suggested State regulations of the plan's approval so that the

parallel development of a suggested State regulation could begin, if such an action is desired.

(2) If the Commission does not approve the rulemaking plan, OSP notifies the Agreement States and the RES CRCPD point of contact notifies the CRCPD Council Chair responsible for suggested State regulations that the plan was not approved.

(d) If a proposed rule is clearly applicable to Agreement State interests, Agreement State involvement will be sought on preliminary versions of the proposed rule through the external rulemaking bulletin board.

1.11 Advisory committee review.

(a) After the proposed rule is approved, the lead office shall forward it to the appropriate advisory committee for review. The advisory committees are the --

- (1) Advisory Committee on Reactor Safeguards;
- (2) Advisory Committee on Nuclear Waste; and
- (3) Advisory Committee on Medical Uses of Isotopes.

(b) The staff shall formally document and respond to any consensus committee comments or recommendations concerning the rulemaking action.

(c) If an individual committee member participates in a rulemaking apart from the committee, the comments received from the individual are maintained as part of the rulemaking record.

(d) The staff shall meet with the appropriate committee, at the committee's request, at any time during the rulemaking process to discuss the staff's rationale for the proceeding.

1.13 Concurrence on a rulemaking action.

(a) Each office director and the General Counsel shall designate an office representative and an alternate for each rulemaking action.

(1) The designee, and his or her alternate in the designee's absence, is responsible for --

(i) Keeping office management informed of the policy issues that could affect office interests or constitute a basis for legal objection and of the designee's proposed position regarding these issues;

(ii) Speaking or signing for his or her office on the rulemaking regarding concurrence or conditions for concurrence or no legal objection by writing the concurrence letter or identifying specific issues that prevent concurrence or no legal objection; and

(iii) Overseeing office review of factual matters in the concurrence document and providing timely feedback during the document development process.

(2) The office designee may interact in the concurrence process in either the traditional mode or as a member of a steering group.

(b) Office concurrence means that --

(1) The office agrees with the overall approach, objective, technical content, and resource impacts of the draft rulemaking document and applicable supporting information.

(2) The rulemaking action does not or will not adversely affect or conflict with other NRC programs or policies.

(3) The office agrees with material that is presented as factual and for which the office has a programmatic basis for judging the accuracy of the material.

(4) The office has reviewed the rulemaking action and agrees that it is consistent with current rules and other authoritative statements of agency

policy, including, for example, consistency in the use of wording, terminology, definitions, and risk standards.

(c) OGC review of rulemaking actions will be consistent with OGC Policy and Procedure Directive 14, which governs OGC review and approval of papers and provides for either concurrence or no legal objection.

(1) From OGC's standpoint, concurrence means that the recommended action is legally sufficient, is consistent with existing policy or is sound future policy, and is supported by OGC.

(2) No legal objection means that the recommended action is legally sufficient but either that OGC has no particular interest in or contribution to make to the policy aspects of the recommendation or that the reviewing attorney disagrees with the recommendation on policy grounds. If the reviewing attorney disagrees with the recommendation on policy grounds, he or she shall formally communicate the policy disagreement and the supporting reasons with the originating office, branch chief or above, or the proposed signer of the document, as appropriate, and to appropriate OGC management.

(3) OGC review and processing may not be held up because of policy disagreements that do not have a legal basis (see paragraph (d)(3) of this section).

(d)(1) An office may not withhold office concurrence or no legal objection on the basis of questions concerning material that is presented as factual except for parts of the material for which the office has a programmatic basis for judging its accuracy of the material. However, the concurring office may provide timely questions or concerns regarding any technical analysis or information that may invalidate or raise doubts about the proposed rule.

(2) An office may not withhold office concurrence or no legal objection on the basis of editorial style or manner of presentation that does not affect the policy recommendations of the rulemaking action. However, the concurring office may provide timely suggestions for revised wording for the optional use of the originating office.

(3) An office may not withhold office concurrence or no legal objection on the basis of policy disagreements that do not have a legal basis. A rulemaking document is considered legally sufficient when all relevant facts are presented and these facts are considered in light of applicable laws. Applicable laws include the Constitution, treaties, statutes, regulations, Executive orders, judicial decisions, agency adjudicatory decisions, contracts and agreements, and binding Commission policy and staff requirements memoranda.

1.15 Scheduling concurrences.

(a) At both the proposed rule and final rule stage, the originating office shall transmit each rulemaking action for which concurrence is being requested to all concurring offices simultaneously. The transmittal must include a hand-carried official hard copy with cover memorandum and an electronic copy through the internal NRC rulemaking bulletin board.

(1) The originating office shall notify the EDO, key technical staff within the concurring office, and the appropriate advisory committee of the availability of the rulemaking action on the internal rulemaking bulletin board.

(2) Each concurring office shall establish an internal logging and concurrence tracking system that is applicable to rulemaking actions. Each concurring office shall log the receipt of the hard copy rulemaking document in the internal tracking system. The designee or the alternate for the rulemaking action shall sign a receipt for the originating office's transmittal.

(3) Concurrence should be requested from all other NRC offices that are affected by or interested in the rulemaking action; OGC; RDB, ADM; the Information and Records Management Branch, Office of the Chief Information Officer (OCIO), to coordinate OMB review and approval of any new or amended information collection requirements; and the Office of Enforcement (OE) to ensure that an appropriate criminal penalty statement is included. OE will determine whether the "criminal penalties" section for each part affected by the rulemaking action must be amended to reflect the rulemaking action. OE also will determine whether any changes to the Enforcement Policy are warranted.

(i) The Office of the Chief Financial Officer reviews rulemaking actions submitted to the Commission to ensure that the resources required to complete and to implement the rulemaking have been properly addressed.

(ii) The OCIO reviews rulemaking actions submitted to the Commission to ensure that potential information technology impacts have been properly addressed.

(ii) The Office of the Inspector General (OIG) reviews rulemaking actions and makes recommendations concerning the impact of the rulemaking on the economy. OIG also makes recommendations concerning efficiency in the administration of programs and operations administered or financed by the agency and concerning the prevention of fraud and abuse in these programs. OIG forwards its comments to the lead office or to the Commission, as appropriate.

(b) Each concurring office shall respond to the originating office by hand-carried memorandum or by NRC mail and through the rulemaking bulletin board within 20 calendar days. The responding office shall --

(1) Concur or provide no legal objection without comment in the rulemaking document;

(2) Concur or provide no legal objection on the provision that specific policy or legal recommendations of the concurring office can be accommodated;

(3) State the policy reasons for withholding concurrence or for the legal objection and present the suggested solutions that would result in concurrence, and send a copy of this memorandum to the Office of the Executive Director for Operations (OEDO); or

(4) State the reasons for being unable to respond on schedule and send a copy of this memorandum to the OEDO.

(c) Within 20 calendar days of the receipt of concurrence memoranda, the proposing office shall --

(1) Provide a final rulemaking proposal, including the proposed or final rule, to the EDO; or

(2) Hold a meeting with the designated representatives of participating offices, or their alternatives, with the appropriate Deputy Executive Director to resolve any impasse that is preventing the presentation of the rulemaking for EDO review.

(d) Within 20 calendar days of receipt of a proposed or final rule, the OEDO shall --

(1) Transmit the proposed or final rule for Commission consideration;

(2) Notify the Commission of the intent to issue the rule under the authority of the EDO; or

(3) Return the rulemaking proposal to the staff for modification or resolution of questions within a specified schedule.

1.17 Commission consideration.

(a) When the rulemaking action is forwarded to the Commission for consideration, the Office of the Secretary (SECY) schedules it for Commission consideration, with or without oral presentations, at a Commission meeting. Usually, Commission meetings on these matters are open to the public under the Government in the Sunshine Act. In some cases, such as those involving classified or safeguards matters, the meeting may be closed to the public. Copies of the Commission paper are sent to every Commission-level office that may have an interest in the regulation. The Commission may approve the regulation as submitted by the EDO, approve the regulation subject to specified changes, disapprove the regulation entirely, or direct that the regulation be revised and resubmitted to the Commission for reconsideration.

(b) The Commission's decision on a regulation is reflected in a staff requirements memorandum (SRM) issued by SECY. If the Commission orders changes to be made in the regulation, the SRM describes these changes and establishes the deadline for resubmission for Commission consideration or submission for signature and publication.

1.19 Processing for publication.

(a)(1) If the Commission approves the rulemaking action, the staff prepares it for publication by making any changes the Commission directed and any remaining editorial or format changes. The staff then prepares the rulemaking package, consisting of the regulation and all necessary accompanying documents. (For additional information on submitting a rulemaking package for publication, see Appendix A to this handbook.) The staff submits the rulemaking package to RDB at least 2 working days before the due date established in the SRM.

(2) RDB conducts a final review of the regulation to ensure compliance with the publication requirements of the OFR and to verify that the regulation is complete. RDB then transmits the regulation to SECY for signature and transmittal to the OFR for filing and publication.

(b) If the regulation is signed by the EDO, the CFO, or the CIO under delegated rulemaking authority, it is routed through RDB for transmittal to the OFR (see Appendix A to this handbook).

(d) RDB forwards letters to appropriate congressional committees, with enclosed copies, of the regulation to the Office of Congressional Affairs (OCA) to ensure that these committees having oversight responsibility for the NRC are notified of the agency's regulatory activities. RDB also forwards to OCA the letters to the Speaker of the House, the President of the Senate, and the General Counsel for the General Accounting Office necessary to comply with Small Business Regulatory Enforcement Fairness requirements applicable to final rules. The originating office coordinates the preparation and issuance of the public announcement with the Office of Public Affairs so that the release of

the public announcement coincides with the publication of the regulation in the Federal Register.

(e) If the regulation is likely to have a significant impact on the quality of the human environment, the staff ensures that the draft or final GEIS, prepared as required under the National Environmental Protection Act and 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," is made available for public comment. If the regulation is subject to the Regulatory Flexibility Act, RDB sends a copy of the regulation and any related analyses to the Chief Counsel for Advocacy of the Small Business Administration. After the regulation is published in the Federal Register, copies of the published document are sent to all affected licensees as well as any interested person who has requested placement on a mailing list for NRC notices.

1.21 Timely resolution of petitions for rulemaking.

(a) The EDO established procedures to ensure that the resolution of a petition for rulemaking is accomplished on a timely basis (see the memoranda from the EDO to office directors dated August 13, 1986, and April 6, 1988). These procedures require that the resolution of a petition for rulemaking occur within 12 months from the date the notice of receipt of the petition was published in the Federal Register. A petition is considered resolved when the lead program office to which the petition is assigned has determined the regulatory decision for the petition: a petition may be resolved by deciding to grant the petition (all or in part) and proceeding with a rulemaking action or by deciding to deny the petition. However, the regulatory decision for a petition (resolution) does not complete the action on the petition. It only represents the decision on the course of action the NRC will follow to complete action on the petition by either granting or denying it. Action on a petition is completed and the petition is closed when the NRC formally grants the petition by completing and publishing the final rule necessary to grant the petitioner's request or when the NRC denies the petition by publishing a notice of this action in the Federal Register and advising the petitioner of this action in writing. Action on a petition also may be completed if the petitioner withdraws the petition.

(b) Each office is required to report the status of each petition for rulemaking for which it is responsible. These status reports, which are submitted to RDB, coincide with the updating of the NRC Regulatory Agenda. The status reports must indicate the scheduled resolution of each petition for rulemaking. The schedule for the resolution of each petition is included in the Agenda. RDB submits a summary report to the EDO that indicates the current status, including the scheduled resolution date, of each petition for

rulemaking. This report includes the reason for any extension of the petition and the new resolution date proposed by the assigned office.

(c) Any proposed extension of the resolution date must be approved by the EDO before the targeted resolution date expires. The EDO reviews the proposed extensions of resolution dates concurrently with the review of completion of rulemaking dates. The EDO may approve the proposed resolution date, direct the assigned office to resolve the petition by the original target date, or establish a new resolution date.

(d) In December 1996, the NRC issued Regulatory Guide 10.12, "Preparation of Petitions for Rulemaking Under 10 CFR 2.802 and Preparation and Submission of Proposals for Regulatory Guidance Documents." This guide encourages industry and the public to submit more detailed supporting information as part of the petition than is required by 10 CFR 2.802 for a petition to be acceptable for processing. If the petition for rulemaking requests amendments that would reduce the regulatory burden through the elimination of requirements that would be marginal to safety and involves requirements that are safety neutral, the submission of more detailed information, as outlined by Regulatory Guide 10.12, would enable the NRC staff to process the petition in a more expeditious manner.



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 9, 2001

CHAIRMAN

The Honorable W.J. "Billy" Tauzin, Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

In response to your letter of February 6, 2001, requesting information on the extent to which the Nuclear Regulatory Commission (NRC) is voluntarily complying with the President's regulatory review plan, I am pleased to provide responses to each of your requests for information.

1. State whether, and to what extent, your agency is voluntarily complying with the President's requests, and explain any decision by your agency not to fully comply.

In light of its particular circumstances, the Commission has not deferred the issuance of any proposed or final regulation or delayed the effective date of any final rule. The NRC is an independent Federal regulatory agency. NRC's regulatory authority resides in a five-member bipartisan Commission that collectively sets the regulatory policy for the agency. The Commission's regulatory philosophy is to ensure that its regulations are needed and are carefully crafted to impose the minimum burdens necessary to protect public health and safety. The Commission will continue to evaluate carefully the regulatory burden and the safety impacts of any regulation requiring Commission approval. The Commission will also continue to comply fully with those provisions of Executive Order 12866, "Regulations Planning and Review," that apply to independent agencies.

2. List all regulations that fall within each of the three categories specified in the President's directive.

The NRC has not sent any new proposed or final regulations to the Office of the Federal Register (OFR) for publication since January 20, 2001. We had no regulations that had been sent to the OFR but not published by January 20, 2001. We have eight regulations that were published before January 20, 2001, but had not become effective as of that date. The enclosed table identifies these eight regulations.

3. A list of those regulations that your agency considers excluded from this review because they were promulgated pursuant to judicial or statutory mandates.

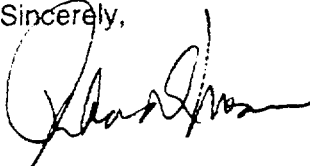
The NRC published one rule that was issued under a statutory mandate. The Commission believes that the final rule entitled "Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance" (10 CFR Part 5: 66 FR 708; January 4, 2001 - Effective February 5, 2001) falls within this category.

4. A list of those regulations that you have requested permission from the Office of Management and Budget (OMB) to exclude because they impact critical health and safety functions. Please also indicate the status of OMB's review of each such request.

The NRC has not requested permission from OMB to exclude any regulation because of its health and safety impact.

Our contact for the status of all NRC rulemaking efforts is Michael T. Lesar (301) 415-7163 or e-mail: mtl@nrc.gov. Please let me know if you have further questions or need additional information.

Sincerely,



Richard A. Meserve

Enclosure: As stated

cc: The Honorable John D. Dingell, Ranking Member

RULES PUBLISHED BUT NOT EFFECTIVE AS OF JANUARY 20, 2001

OFFICE	RULE TITLE	DESCRIPTION	F.R. CITATION & DATE	EFFECTIVE DATE
NMSS*	List of Approved Spent Fuel Storage Casks: Fuel Solutions, Addition (Part 72)	The final rule adds the FuelSolutions cask system to the list of approved spent fuel storage casks. This amendment allows holders of power reactor operating licenses to store spent fuel in the FuelSolutions cask system under a general license.	66 FR 3445; 01/16/2001	02/15/2001
	Requirements for Certain Generally Licensed Devices Containing Byproduct Material (Parts 30, 31, 32)	The final rule amends the regulations governing the use of byproduct material in certain detecting, measuring, gauging, or controlling devices. The final rule includes explicit provisions for a registration authorized under provision of the existing regulations, adds a registration fee, and modifies the reporting, recordkeeping, and labeling requirements for specific licensees that distribute the generally licensed devices. The final rule is intended to allow the NRC to better track general licensees and the devices that they possess.	65 FR 79162; 12/18/2000	02/16/2001
	List of Approved Spent Fuel Storage Casks: TN-32, Revision (Part 72)	The direct final rule revises the Transnuclear West, Inc., TN-32 cask system listing within the list of approved spent fuel storage casks. The amendment allows holders of power reactor operating licenses to store spent fuel in the cask under revised conditions.	65 FR 75853; 12/05/2000	02/20/2001
	List of Approved Spent Fuel Storage Casks: NAC-UMS, Revision (Part 72)	The direct final rule revises the NAC International Universal Storage System NAC-UMS cask system listing within the list of approved spent fuel storage casks. The amendment allows holders of power reactor operating licenses as general licensees to store PWR design basis fuel assemblies in accordance with revised technical specifications and Maine Yankee site-specific spent fuel in the NAC-UMS cask system.	65 FR 76896; 12/07/2000	02/20/2001

*Office of Nuclear Material Safety and Safeguards

RULES PUBLISHED BUT NOT EFFECTIVE AS OF JANUARY 20, 2001

OFFICE	RULE TITLE	DESCRIPTION	F.R. CITATION & DATE	EFFECTIVE DATE
<u>NRR*</u>	Consideration of Potassium Iodide in Emergency Plans (Part 50)	The final rule amends the emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule requires that consideration be given to including potassium iodide as a protective measure for the general public that would supplement sheltering and evacuation. Potassium iodide would help prevent thyroid cancers in the unlikely event of a major release of radioactivity from a nuclear power plant.	66 FR 5427; 01/19/2001	04/19/2001
	Changes, Tests, and Experiments (Part 50 - §50.59)	A document that confirms the effective date of and announces the availability of guidance on a previously published final rule was published in the Federal Register on December 13, 2000 (65 FR 77773). The final rule, published October 4, 1999 (64 FR 53582), amends the regulations concerning the authority for licensees of production or utilization facilities to make changes to the facility or procedures, or to conduct tests or experiments without prior NRC approval.	64 FR 53582; 10/04/1999	Effective Date Confirmed 65 FR 77773; 12/13/2000 - Effective 03/13/2001
	Reporting Requirements for Nuclear Power Reactors and Independent Spent Fuel Storage Installations at Power Reactor Sites (Part 50 - §50.72)	The final rule amends the event reporting requirements for nuclear power reactors. The final rule reduces or eliminates the unnecessary reporting burden associated with events of little or no safety significance and better aligns event reporting requirements with the type of information the NRC needs to carry out its safety mission.	65 FR 63769; 10/25/2000	Became effective 01/23/2001

*Office of Nuclear Reactor Regulation

RULES PUBLISHED BUT NOT EFFECTIVE AS OF JANUARY 20, 2001

OFFICE	RULE TITLE	DESCRIPTION	F.R. CITATION & DATE	EFFECTIVE DATE
<u>SBCR*</u>	Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance (Part 5)	The final rule adds a list of the types of Federal financial assistance activities administered by the NRC under Title IX of the Education Amendments of 1972, as amended. Title IX prohibits recipients of Federal financial assistance from discriminating on the basis of sex in education programs or activities. The publication of this list complies with a requirement contained in Subpart F of the common rule concerning this matter jointly issued by NRC and a number of Federal agencies.	66 FR 708; 01/04/2001	Became effective 02/05/2001

*Office of Small Business and Civil Rights

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U.S. House of Representatives
Room 2125, Rayburn House Office Building
Washington, DC 20515-6115

February 6, 2001

The Honorable Richard A. Meserve
Chairman
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Mailstop 016C1
Rockville, Maryland 20852

Dear Chairman Meserve:

On January 20, 2001, President Bush ordered a regulatory review plan throughout the Executive Branch, and requested that independent agencies voluntarily participate in this effort. This plan included several specific actions:

1. That no new proposed or final regulation be sent to the Office of Federal Register (OFR) for publication until it has been approved by an appointee of the Bush Administration;
2. That regulations already sent to OFR but not yet published be withdrawn and subject to such Bush Administration review; and
3. That the effective date of regulations already published by OFR be temporarily postponed for 60 days to permit such review.

Excepted from this order are regulations that were promulgated pursuant to statutory or judicial deadlines, as well as regulations that impact critical health and safety functions, if approved by the Office of Management and Budget (OMB) for exclusion.

Given that many of your agency's programs fall within the oversight jurisdiction of this Committee, I would like to be informed as to those regulations that are covered by the President's directive. Accordingly, please provide the following information to the Committee by Friday, February 9, 2001:

1. State whether, and to what extent, your agency is voluntarily complying with the President's requests, and explain any decision by your agency not to fully comply.
2. A list of those regulations that fall within each of the three categories specified above.

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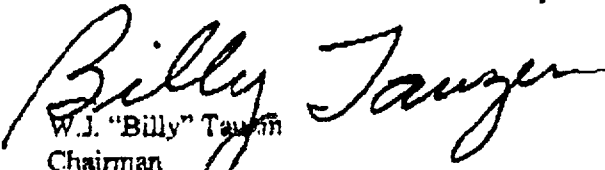
The Honorable Richard A. Mccrvc

Page 2

3. A list of those regulations that your agency considers excluded from this review because they were promulgated pursuant to judicial or statutory mandates.
4. A list of those regulations that you have requested permission from OMB to exclude because they impact critical health and safety functions. Please also indicate the status of OMB's review of each such request.

If you have any questions about these requests, please contact Mr. Mark Paoletta, Chief Counsel for Oversight and Investigations, at (202) 225-2927. Thank you for your cooperation in this matter.

Sincerely,


W.J. "Billy" Tauzin
Chairman
Committee on Energy and Commerce

cc: The Honorable John D. Dingell, Ranking Member

Congress of the United States
House of Representatives
Washington, DC 20515

February 22, 2001

The Honorable Richard A. Meserve
Chairman
Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, Maryland 20852

Dear Chairman Meserve:

On January 20, 2001, White House Chief of Staff Andrew H. Card, Jr., issued a memorandum outlining the new Administration's regulatory review plan. This plan calls for Federal agencies to withhold making effective any new regulation or taking action on any pending regulation unless otherwise authorized to proceed by the Office of Management and Budget (OMB) or a new Bush Administration appointee. Speaking about the new role for OMB in regulatory affairs, OMB's newly confirmed Director, Mitchell E. Daniels, Jr., told U.S. News and World Report "...that he is resurrecting OMB's tough-guy role. Every budget, rule, and regulation will face a 'second opinion' before being OK'd." *Washington Whispers*, U.S. News and World Report (February 19, 2001).

In addition to departments and agencies of the Executive Branch, Chief of Staff Card's memorandum asks that independent agencies, such as yours, participate "voluntarily" in this regulatory review "in the interest of sound regulatory practice." Let us emphatically and clearly state that there are no circumstances where it would be appropriate for an independent agency to "voluntarily" or otherwise submit its regulatory actions for review and approval to OMB or to any other Executive Branch agency or official. Your agency's independent status is not something you, or this Administration, can choose to disregard. Rather, it is based in statutory law that was passed by the Congress and signed by former Presidents. We, therefore, urge you to preserve and to protect the independence conferred on your agency by Congress, despite requests to the contrary from this or any other Administration.

To better understand the current status of your agency's relationship with the new Administration, we ask that you provide us with your written responses to the following requests for information, along with any other material relevant to our inquiry, no later than Friday, March 2, 2001:

- (1) Please provide a copy of any written communication (including electronic) you or any other employee of your agency has received from any official or employee of

2/26...To EDO/OGC to Prepare Response for Chairman's Signature...
Date due Comm: March 1...Cpy to: Chairman, Comrs, RF, OCA to Ack
...01-0126...EDO...Coordinate with OGC...COMMISSION CORRESPONDENCE

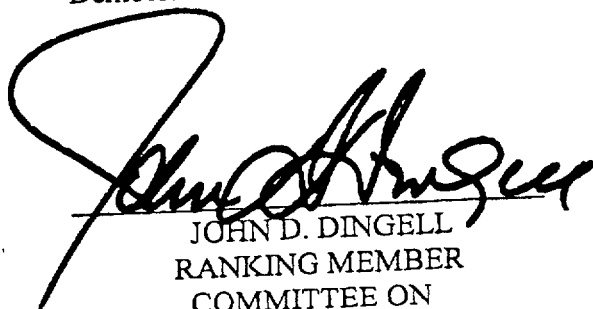
The Honorable Richard A. Meserve
Page 2

the Executive Branch requesting that your agency submit regulatory proposals to OMB as part of the new Administration's regulatory review plan. Please identify both the source of any such communication and the agency official or employee to whom it was directed.

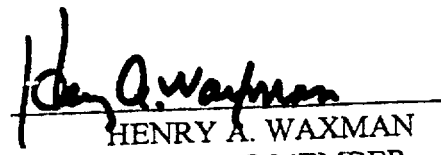
- (2) Please identify any verbal communication from any official or employee of the Executive Branch requesting that your agency comply with any aspect of the new Administration's regulatory review plan. Please identify both the Executive Branch official or employee and the agency official or employee who received any such verbal communication.
- (3) Please provide a copy of any written communication (including electronic) you or any other employee of your agency has received from any official or employee of the Executive Branch requesting that your agency comply with any procedures other than those procedures developed and carried out by your agency in compliance with its statutory mandate to conduct its regulatory actions in an independent manner.
- (4) Please provide a copy of any written response (including electronic), as well as a written description of any verbal response, you or any other employee of your agency has made to any written or verbal request from any official or employee of the Executive Branch that your agency comply with any aspect of the new Administration's regulatory review plan.
- (5) Please describe the procedures your agency follows in adopting rules and regulations.

Thank you for your cooperation. If you have any questions regarding this matter, you may contact us or have your staff contact Bruce Gwinn, Committee on Energy and Commerce Democratic Staff, at (202) 226-3400 or Michelle Ash, Committee on Government Reform Democratic Staff, at (202) 225-5420.

Sincerely,



JOHN D. DINGELL
RANKING MEMBER
COMMITTEE ON
ENERGY AND COMMERCE



HENRY A. WAXMAN
RANKING MEMBER
COMMITTEE ON
GOVERNMENT REFORM

The Honorable Richard A. Meserve
Page 3

cc: The Honorable W.J. "Billy" Tauzin, Chairman
Committee on Energy and Commerce

The Honorable Dan Burton, Chairman
Committee on Government Reform